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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MAX R. MOTYKA, RICK HARNISH, STEPHEN D. ASHMEAD
and H. DEWAYNE ASHMEAD

Appeal 2009-005416
Application 10/829,468
Technology Center 1600

Decided: September 11, 2009

Before DEMETRA J. MILLS, RICHARD M. LEBOVITZ, and STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to methods of preparing and administering a metal amino acid chelate. The Patent Examiner rejected the claims as anticipated or as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The invention concerns amino acid chelates used for mineral nutrition. (Spec. 2:2-4.) According to the Specification, the structure, chemistry, bioavailability, and various applications of amino acid chelates are "well documented in the literature." (*Id.* at 3:22-23, citing references.) The Specification further discloses that "[i]ssues surrounding the use of genetically modified organisms, or GMOs, have become more prevalent in recent years due to the great advances in genetic engineering" (*id.* at 4:10-11), and "it would be an advancement in the art to provide non-GMO metal amino acid chelates" (*id.* at 5:1-2).

Claims 34-53, which are all the pending claims, are on appeal. Claims 34 and 43 are representative and read as follows:

34. A method of preparing a non-GMO metal amino acid chelate, comprising:

    a) selecting an amino acid source determined to be non-GMO;
    b) selecting a metal source determined to be non-GMO; and
    c) chelating an amino acid of the amino acid source to a metal of the metal source, thereby forming a non-GMO metal amino acid chelate.

43. A method of administering a metal amino acid chelate, comprising:

    a) formulating a non-GMO metal amino acid chelate by:
        i) selecting an amino acid source determined to be non-GMO,
        ii) selecting a metal source determined to be non-GMO, and
        iii) chelating an amino acid of the amino acid source to a metal of the metal source, thereby forming the non-GMO metal amino acid chelate; and

    b) administering the non-GMO metal amino acid chelate to the subject.

The Examiner rejected the claims as follows:

• claims 34-36, 41-45 and 50-53 under 35 U.S.C. § 102(b) as anticipated by Hsu;[1]

• claims 34-36, 41-45, 52 and 53 under 35 U.S.C. § 102(b) as anticipated by Ashmead '424;[2]

• claims 43-45, 50, 51 and 53 under 35 U.S.C. § 102(b) as anticipated by Ashmead '427;[3] and

• claims 34, 37-40, 43 and 46-49 under 35 U.S.C. § 103(a) as unpatentable over the combined teachings of Hsu and Izumi.[4]

Dependent claims 35-42 and 44-53 have not been argued separately and therefore stand or fall with independent claim 34 or 43. 37 C.F.R. § 41.37(c)(1)(vii).

ANTICIPATION

The Issues

The Examiner's positions are:

- Hsu taught metal amino acid chelates and their use to deliver desirable metal ions to plants and human beings; and Hsu's preparation and administration of an iron/citrate/glycine chelate to tomato plants anticipated Appellants' claimed methods. (Ans. 3-4.)

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[1] U.S. Patent No. 5,504,055, issued to Hsinhung J. Hsu, Apr. 2, 1996.
[2] U.S. Patent No. 6,426,424 B1, issued to Stephen D. Ashmead et al., Jul. 30, 2002.
[3] U.S. Pat. No. 4,725,427, issued to H. DeWayne Ashmead et al., Feb. 16, 1988.
[4] Yoshiharu Izumi et al., *Production and Utilization of Amino Acids*, 17 ANGEW. CHEM. ED. ENGL. 176-83 (1978).

- Ashmead '424 taught compositions and methods of preparing amino acid chelates; and Ashmead's disclosure of preparing and administering the chelates to plants anticipated Appellants' claimed methods. (*Id.* at 4-5.)
- Ashmead '427 taught the preparation of a vitamin and mineral composition comprising amino acid chelate for use in a flavored drink; and anticipated Appellants' claimed methods. (*Id.* at 5-6.)

Appellants contend that none of the three references disclose each and every element of the claims. (App. Br. 10-11.) That is, none of the references direct one of ordinary skill in the art "to specifically choose a metal or amino acid from a non-genetically modified organism." (*Id.* at 12.) Appellants contend that the Examiner has misunderstood the claims, because "[b]oth independent method claims require an affirmative non-GMO determination." (*Id.*) "The fact that a non-GMO source could be used in the prior art does not implicitly or explicitly teach the recited element of an affirmative non-GMO determination." (*Id.*)

The issue with respect to the three anticipation rejections whether the evidence supports the Examiner's finding that the prior art necessarily disclosed "selecting an amino acid source determined to be non-GMO amino acid" and "selecting a metal source determined to be non-GMO"?

Findings of Fact

1. Hsu taught metal amino acid chelates for "delivering high levels of desirable metal ions to plants, animals or human beings." (Col. 1, ll. 44-46.)

2. Hsu's process for preparing metal amino acid chelates comprised dissolving a water soluble salt of the desired metal ion in deaerated water, adding the salt solution to solution of amino acid, and adjusting the pH. (Col. 1, l. 65 – col. 2, l. 4.)
3. Hsu taught administering metal amino acid chelate to plants. (Col. 7, l. 56 – col. 8, l. 13.)
4. Hsu did not teach selecting a genetically modified organism as a source for amino acids or metals.
5. Ashmead '424 taught methods of preparing metal amino acid chelates. (Abstract.)
6. Ashmead '424 taught administering metal amino acid chealtes to plants and animals. (Col. 7, ll. 53-63.)
7. Ashmead '424 did not teach selecting a genetically modified organism as a source for amino acids or metals.
8. Ashmead '427 taught preparing a metal amino acid chelate. (Col. 5, l. 57 – col. 6, l. 18.)
9. Ashmead '427 taught administering metal amino acid chelate via a "pleasant tasting, lightly carbonated lemon-lime flavored drink." (Col. 10, ll. 1-5.)
10. Ashmead '427 did not teach selecting a genetically modified organism as a source for amino acids or metals.

Principles of Law Relating to Anticipation

"Anticipation is a question of fact, and is determined by first construing the claims and then comparing the properly construed claims to the prior art." *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1346

(Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999).

Analysis of the Anticipation Issue

Amino acid chelates and their uses have been well documented since at least 1982. (Spec. at 3-4, incorporating literature and patents by reference.) Prior to the invention of genetically modified organisms (GMOs), amino acid chelates were made with amino acids and metals prepared from non-GMO sources. The Specification states that "[i]ssues surrounding the use of genetically modified organisms, or GMOs, have become more prevalent in recent years due to the great advances in genetic engineering." (*Id.* at 4:10-12.)

According to the Specification, "it would be an advancement in the art to provide non-GMO metal amino acid chelates and non-GMO formulations that contain amino acid chelates." (*Id.* at 5:1-3.) However, the Examiner established, as evidenced by each of the cited Hsu and Ashmead patents relied upon in the rejections, that the state of the art when Appellants filed their application was that the preparation of metal amino acid chelates from non-GMO sources was known in the art, as were methods of administering the chelates. That is, rather than being the advancement the Specification describes, Appellants' claims would withdraw known methods of making and administering metal amino acid chelates from the public domain.

Appellants argue that none of the Examiner's citations show that the prior art taught the claimed "selecting an amino acid [or metal] source

determined to be non-GMO." Thus, Appellants argue, their claims include "affirmative" steps unknown in the prior art. (App. Br. 12.) No chemical manipulation is required by the term "determined," as the Specification discloses: "[d]etermining whether a composition or its source is non-GMO indicates that some type of evaluative step be performed." (Spec. 10:4-5.) "[A]n evaluation step can include steps such as reviewing literature . . . ." (*Id.* at 10:7.) Thus, a manipulative step such as a test or assay is not required. In this case, if an artisan performed the evaluative step of reviewing prior art, such as Hsu or either of the Ashmead patents, it would have resulted in using a non-GMO source, because none of those references taught the extra step of finding and selecting a GMO source.

It is well-settled that merely recognizing something that was not known before is insufficient to render an old process re-patentable. *Cruciferous Sprout*, 301 F.3d at 1351. Here, "selecting . . . source determined to be non-GMO" does not distinguish the claimed method over the methods disclosed in Hsu or either Ashmead patent. The only difference is that Appellants have recognized an inherent property of the old processes.

Our conclusion is consistent with the line of cases in which anticipation was found based on inherency.

> [A] prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent to it. . . . Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.

MEHL/Biophile, 192 F.3d at 1365. The methods Appellants claim was in use, although those of ordinary skill in the art may not have recognized they were working with non-GMO sources. In *Perricone v. Medicis Pharm.*

Corp., 432 F.3d 1368, 1378-79 (Fed. Cir. 2005), a method claim preamble which required "preventing sunburn damage to exposed skin surfaces," was found satisfied by a prior art skin composition which had been applied to skin surfaces, but for a different purpose. "[T]he new realization alone [that the old composition would prevent sunburn damage] does not render the old invention patentable." *Perricone*, 432 F.3d at 1377.

Appellants claims define the old processes of making and administering amino acid chelates with the same materials for the same purposes. Our reasoning is consistent with the court's reasoning in the *Cruciferous Sprout* case, 301 F.3d at 1351-52. There, the disputed claim had steps of "identifying" seeds "containing high Phase 2 enzyme-inducing potential" and then sprouting the seeds. (*Id.*) The validity of the claim was challenged because seeds having high Phase 2 enzyme-inducing potential had been grown and eaten prior to the patent's filing date. The patent holder argued that its claims were not anticipated because the prior art did not "specify which cultivars should be sprouted." (*Id.*, 301 F.3d at 1351.) The court gave no weight to the selection argument, concluding "[i]t is unnecessary for purposes of anticipation for the persons sprouting these particular cultivars to have realized that they were sprouting something . . . high in Phase 2 enzyme-inducing potential." (*Id.*) The recitation in the claim of a step that required identification of the sprout's properties did not persuade the court that the inventor had done anything more than "recognize[] something about sprouts that was not known before." (*Id.*) Likewise, Appellants' argument does not persuade us that the methods claimed have a manipulative difference from the prior art methods. *See also*, *Bristol-Myers Squibb Co. v. Ben Venue Laboratories*, where the court

treated a claim expression ("method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity") as non-limiting because "[t]he expression does not result in a manipulative difference in the steps of the claim." 246 F.3d 1368, 1375-76 (Fed. Cir. 2001.)

In sum, we agree with the Examiner that "selecting a source . . . determined to be non-GMO" does not distinguish the amino acid and metal sources selected in the claims from the sources selected in the prior art. Put another way, the selected sources "determined to be non-GMO" are the sources that were known and selected in the prior art.

OBVIOUSNESS

The Obviousness Issue

The Examiner found that Hsu did not expressly disclose a method wherein the amino acid to be chelated was prepared by: 1) a method other than hydrolysis; 2) synthetically; 3) fermentation; or 4) protein hydrolysis of a non-GMO protein. (Ans. 7.) The Examiner found that Izumi taught "multiple methods of producing amino acids including enzymatic, fermentation, extraction (protein hydrolysis) and synthetic methods." (*Id.*) The Examiner concluded that it would have been obvious to a person of ordinary skill in the art who wished to produce Hsu's chelate to obtain the amino acid via one of the methods taught by Izumi. (*Id.*)

Appellants contend that the rejection "failed to show that each and every element of the claimed invention is contained in the combined references." (App. Br. 16.) That is, the rejection "failed to show any language in any reference in the current [O]ffice action related to affirmative

steps to select non-GMO materials for use in preparing the non-GMO chelates." (*Id.* at 17.)

The issue with respect to this rejection is whether selecting a "source determined to be non-GMO" renders the claims nonobvious.

Further Findings of Fact

11. Izumi taught that multiple methods of producing amino acids were available. (Abstract.)
12. The methods Izumi reviewed included synthesis from raw materials. (Page 179.)

Principles of Law Relating to Obviousness

A rejection for obviousness must include "articulated reasoning with some rational underpinning to support the legal conclusion." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

When combining references, the proper question to ask is whether a person of ordinary skill in the art, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to combining the prior art teachings. *KSR*, 550 U.S. at 424; *see also In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (the desirability of the combination may arise from nature of the problem, teachings of references, or the ordinary knowledge of those skilled in the art). "[A] combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. . . . [I]f a technique has been used to improve one device, and a person of ordinary skill in the art would

recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill." *KSR*, 550 U.S. at 401.

An invention "suggested by the prior art, and hence, potentially in the possession of the public, is [not] patentable . . . because it also possesses an inherent, but hitherto unknown function which [Applicants] claim to have discovered. . . . A patent on such a structure would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art." *In re Wiseman*, 596 F.2d 1019, 1023 (CCPA 1979).

Analysis of the Obviousness Issue

Appellants rely on the claim language "selecting" a source "determined to be non-GMO." Thus, Appellants argue the Examiner's rejection did not show that the selecting step was taught or suggested by the references. For the reasons already discussed, we do not agree with Appellants that the "affirmative" selecting step constitutes a manipulation step that distinguishes over the prior art. We agree with the Examiner that a person of ordinary skill in the art at the time of the invention, who wished to practice Hsu's methods, would have found it obvious to use the synthetic methods Izumi reviewed as a source of amino acids. It is undisputed that synthesis from raw materials is a non-GMO source. Appellants' "claims would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art." *Wiseman*, 596 F.2d at 1023.

CONCLUSIONS OF LAW

The claim phrases "selecting an amino acid source determined to be non-GMO" and "selecting a metal source determined to be non-GMO" do not distinguish the amino acid and metal sources selected in the claims from the sources selected in the prior art.

The evidence supports the Examiner's finding that each of Hsu, Ashmead '424, and Ashmead '427 necessarily disclosed "selecting an amino acid source determined to be non-GMO amino acid" and "selecting a metal source determined to be non-GMO."

The language "selecting . . . source determined to be non-GMO" does not make the claims nonobvious.

SUMMARY

We affirm the rejections of claims 34-36, 41-45 and 50-53 under 35 U.S.C. § 102(b) as anticipated by Hsu; claims 34-36, 41-45, 52 and 53 under 35 U.S.C. § 102(b) as anticipated by Ashmead '424; claims 43-45, 50, 51 and 53 under 35 U.S.C. § 102(b) as anticipated by Ashmead '427; and claims 34, 37-40, 43 and 46-49 under 35 U.S.C. § 103(a) as unpatentable over the combined teachings of Hsu and Izumi.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

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